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10/624,080	07/21/2003	Ganjam V. Kalpana	96700/819	5994

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EXAMINER	
HORNING, MICHELLE S	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/624,080	KALPANA, GANJAM V.	
	Examiner	Art Unit	
	Michelle Horning	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,24,25,31,32,41,49,62,72 and 81* is/are pending in the application.

4a) Of the above claim(s) *32,41,49,62,72 and 81* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 9-19, 24-25 and 31* is/are rejected.

7)☒ Claim(s) *6, 8 and 31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of Group I in the reply filed on 6/20/2006 is acknowledged.

This office action is in response to communication filed 6/20/2006. The status of the claims is as follows: claims 1-19, 24-25 and 31 are under current examination, claims 20-23, 26-30, 33-40, 42-48, 63-71 and 73-80 have been cancelled, and claims 32, 41, 49, 62, 72 and 81 are drawn to non-elected inventions. All claims 1-19, 24-25, 31-32, 41, 49, 62, 72 and 81 are pending.

Claim Rejections

35 U.S.C. 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by "wherein the cell further comprises HIV-1". Is the cell infected with the HIV-1 virus? Does the cell comprise HIV-1 capsid proteins? This claim must be corrected so that it clearly points out how the cell is related to HIV-1.

Claim 19 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by the

recitation "the cell is *treated* with the vector". Treated does not necessarily mean transfected or transformed. Correction is required.

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 31 depends from cancelled claim 26.

35 U.S.C. 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1-9 are drawn to a product of nature (i.e. all peptides in nature "comprising an Rpt1 domain of an INI1/hSNF5). Identifying the peptide as either "isolated" or "purified" in the claims should eliminate this rejection.

Claims 10-16 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 10-16 are drawn to a product of nature (i.e. all cells "comprising the peptide of claim 1"). Of note, results from the inventor's US Patent 5,872,213 "suggest that the ini-1 gene is very widely, and possibly ubiquitously, expressed" as determined by isolating INI-1 RNA from a number of tissues including peripheral blood lymphocytes, colon, small intestine, ovary, testis, prostate, thymus and spleen (col. 9, under Expression of the Ini-1 mRNA in mammalian

cells). According to US Patent 5,872,213, all cells comprise this peptide and thus, according to the instant application all cells are claimed. Further, it is not clear whether the cell is *in vivo* or *in vitro* in the claim; the specification of the instant application discloses data, methods, materials and working examples from isolated cells or cell lines. Thus, the above claims are rejected.

35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-17, 19 and 24-25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US Patent 5,872,213. The claim limitations of the instant application are:

1. a peptide comprising SEQ ID NO: 2, 3 or 5;

2. the peptide is in human cells, including T cell and hematopoietic stem cell;

3. the peptide does or does not comprise a non-peptide moiety;

4. the peptide is present in sufficient amount to inhibit replication or virion production of HIV-1 in the cell, or spread of HIV-1 to another cell;

5. a cell expresses the peptide;

6. a vector encoding SEQ ID NO:2 without any non-peptide moiety;

7. a vector encoding SEQ ID NO:2 without any non-peptide moiety is expressed in a human cell;

8. a vector encoding SEQ ID NO:2 without any non-peptide moiety is expressed in a human cell in amounts sufficient to inhibit replication or virion production of HIV-1 in the cell; and

The limitations above are met in the inventor's US Patent 5,872,213. SEQ ID NO:2 of US Patent 5,872,213 comprises SEQ ID NO:2, 3 and 5 of the instant application, fulfilling limitation 1 and limitation 3 (in part).

In column 9, lines 16-47, US Patent 5,872,213 states that "the cDNA inserts (INI-1) recovered in the **GAL4AC plasmids** were derived from mRNAs of the HL60 human monocytic-myelocytic cell line, suggesting that the gene must be expressed in at least moderate levels in this tumor line. The sequences present in the cDNA insert might include only a portion of the complete mRNA. To determine how widely the ini-1 mRNA was expressed, and to determine the size of the full-length transcript, RNAs were isolated from HeLa cells, a human B-cell tumor line (CB33), and a **human T-cell line (Hut78)**, and analyzed by Northern blot hybridization using an ini-1 probe (FIG. 2). RNAs from all three lines contained a single major species detected with the probe, migrating at approximately 2.0 kb. In addition, the HeLa and CB33 lines contained a minor species migrating at approximately 4.0 kb. To determine whether the ini-1 gene was expressed in normal tissues, RNAs isolated from **peripheral blood lymphocytes**, colon, small intestine, ovary, testis, prostate, thymus and spleen were separated by electrophoresis, blotted and probed as before (FIG. 2). All 8 tissues expressed substantial levels of the 2.0 kb mRNA. The level of expression of the mRNA was similar in all the tissues tested. In addition to the major mRNA species, long exposures of the autoradiographs revealed low levels of a species migrating at 1.25 kb present in the spleen, and similarly low levels of a species migrating at about 4 kb in the thymus, prostate and testes. These results suggest that the ini-1 gene is very widely, and possibly ubiquitously, expressed, and that the major transcript in all tissues is approximately 2.0 kb in length. Additional transcripts with alternative

structures, or transcripts from closely related genes, may be present in some tissues." This recitation fulfills limitiations 2, 5, 6 and 7 above in that the peptide is found in human cells, such as T cells and hematopoietic stem cells, and the vector or GAL4AC plasmid encoding SEQ ID NO:2, 3 and 5 is expressed in a human cell.

The limitations 3 and 8 are met in the following recitation (col.5, lines 61-67 to col. 6, lines 1-4) of US Patent 5,872,213 "The invention also provides for a method of disrupting a retrovirus life cycle in a cell which comprises contacting the cell with a compound which is capable of disrupting a retrovirus integrase protein-Ini-1 protein interaction so as to thereby disrupt the retrovirus life cycle. The compound contacting the cell may be a soluble Ini-1 fragment, a HIV-1 IN fragment or a chemical molecule. The soluble Ini-1 fragment may be a small peptide of 4 to 20 amino acids in length, in one preferred embodiment there may be 6 to 12 amino acids. Other fragments may include **non-peptide mimics** of Ini-1 fragments." This recitation expresses the use of peptide and non-peptide moieties to disrupt HIV-1.

"Finally, the identification of a host protein as interacting with the HIV-1 IN raises the possibility that it may be used as a novel route to inhibit viral replication. If the protein serves to stimulate integration, then drugs which could block the interaction might retard viral spread. In addition, it might be possible to generate dominant negative alleles of ini-1, perhaps encoding small fragments of the protein, that bind inappropriately to IN and block its activity" is a recitation taken from US Patent 5,872,213 (col. 13, lines 38-45). This recitation overcomes limitation 4 and further overcomes limitation 8.

CONCLUSION

Claim 8 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 570-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for unpublished application is available through Private PAIR only. For more information about PAIR system, see htt://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michelle Horning
Patent Examiner

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